

REMARKS

Claims 1-9, 17-20 and 24 were pending in this application. Claims 1 and 2 are currently amended. Claims 1-9, 17-20 and 24 are pending and presented for examination.

Amendments to the claims

Claims 1 and 2 are amended to recite methods for detecting a current *Helicobacter pylori* infection. The claims are amended without any intention of disclaiming equivalents thereof. Support for the amendment is found in the originally-filed application at, for example, page 2 and in original claim 1.

Applicant submits that no new matter is introduced by these amendments.

Interview Summary

Applicant thanks Examiner Chunduru for the telephonic interview of September 4, 2003, with the undersigned agent and Daniel A. Wilson, in which the outstanding rejections under 35 U.S.C. § 102 were discussed. Applicant has attempted in this paper to reflect the substance of the telephonic interview and invites Examiner Chunduru to contact the undersigned if there are any outstanding issues to be resolved.

Claim rejections under 35 U.S.C. § 102

Claims 1-6, 8 and 18 stand rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Gramley *et al.* (1999) *J. Clin. Microbiol.* 37(7):2236-2240 (“Gramley”). Claims 1-6, 8, 18 and 20 stand rejected under 35 U.S.C. § 102 as allegedly anticipated by WO 00/29618 (“Powell”). Applicant traverses these rejections.

As amended, claim 1 relates to methods for detecting a current *Helicobacter pylori* infection. As discussed in the present application at page 2 and in the examples, the present invention permits distinguishing a current *Helicobacter pylori* infection from a past, cured infection. The method includes identifying a patient as having a current infection if the nucleic acid is present in a length and an amount indicative of infection, the amount exceeding an amount indicative of an absence of current *Helicobacter pylori* infection.

Gramley does not teach identifying a patient as having a current infection. Indeed, Gramley admits that “additional testing of stools after treatment of *H. pylori* infection is planned to determine if the assay is helpful in determining eradication of the microorganism” (Gramley, p. 2239). Applicant submits that Gramley was incapable of identifying a patient as having a current infection, as Gramley had not identified an assay as distinguishing current infections from past infections. Applicant further submits that Gramley had reason to question his ability to identify a patient as having a current infection, as others before (and after) Gramley reported difficulty using PCR to distinguish a current infection from an eradicated one for several weeks after eradication therapy (see, e.g., Makristathis *et al.* (1998) J. Clin. Microbiol. 36:2772-2774 (IDS reference C9; cited in Gramley as reference 10) and Makristathis *et al.* (2000) J. Clin. Microbiol. 38(10):3710-3714, a copy of which is attached as IDS reference C61). Applicant submits that because Gramley does not teach a method for detecting a current infection, does not teach identifying a patient as having a current infection, and does not teach distinguishing an amount indicative of an absence of current infection, Gramley does not anticipate claim 1 or any claim depending from claim 1 (e.g. claim 8).

Applicant submits that Powell similarly fails to anticipate claim 1. Applicant notes that the teachings of Gramley and Powell are similar: the inventors of Powell are also among the authors of Gramley, the documents are of similar dates, and some portions of the documents are nearly identical. Like Gramley, Powell does not teach a method for detecting a current infection, does not teach identifying a patient as having a current infection, and does not teach distinguishing an amount indicative of an absence of current infection. Accordingly, Applicant submits Powell does not anticipate claim 1 or any claim depending from claim 1 (e.g. claim 8).

Applicant submits that neither Gramley nor Powell anticipates claim 2. Like claim 1, claim 2 relates to a method for detecting a current *Helicobacter pylori* infection. Accordingly, for the reasons discussed above, Applicant submits that claim 2 is not anticipated by Gramley or Powell. Furthermore, the method of claim 2 includes detecting a high-integrity *Helicobacter pylori* nucleic acid. In the present application, “high-integrity nucleic acid” refers to a nucleic acid having about 175 base pairs or more (application, p.2). Neither Gramley nor Powell teaches detecting a nucleic acid having about 175 base pairs or more. Applicant therefore submits that

neither Gramley nor Powell anticipates claim 2 or any claim depending from claim 2 (e.g. claims 3-6).

Applicant submits that neither Gramley nor Powell anticipates claim 18. Claim 18 relates to a method for detecting a *Helicobacter pylori* infection in a patient; the method includes detecting a human nucleic acid in a patient stool sample and identifying the patient as having disease if the length of the nucleic acid is indicative of infection. Gramley and Powell teach an assay for *H. pylori* based on detection of *H. pylori* DNA. Gramley and Powell detect a human nucleic acid merely as a positive control, even in samples from uninfected patients (based on histology, serology, and DNA analyses), to confirm “the presence of amplifiable DNA” (Gramley, Figure 2). Neither Gramley nor Powell teaches identifying a patient as having disease if the length of a human nucleic acid is indicative of infection. Accordingly, Applicant submits that neither Gramley nor Powell anticipates claim 18.

Claim rejections under 35 U.S.C. § 103

Claims 7, 9, 19 and 24 stand rejected under 35 U.S.C. § 103 as allegedly unpatentable over Gramley in view of U.S. Patent No. 6,143,529 (“Lapidus”). Applicant traverses these rejections.

Like claim 1, from which they depend, claims 9, 19 and 24 relate to methods for detecting a current *Helicobacter pylori* infection; the method includes identifying a patient as having a current *Helicobacter pylori* infection if a nucleic acid is present in a length and an amount indicative of infection, the amount exceeding an amount indicative of an absence of current *Helicobacter pylori* infection. Applicant submits Gramley does not teach or suggest a method for detecting a current *Helicobacter pylori* infection, does not teach or suggest identifying a patient as having a current *Helicobacter pylori* infection, does not teach or suggest distinguishing an amount indicative of an absence of current *Helicobacter pylori* infection, and does not provide a reasonable expectation of success in doing so. Lapidus does not relate to the detection of a current *Helicobacter pylori* infection and therefore fails to remedy the deficiencies of Gramley. Accordingly, Applicant submits that even in combination Gramley and Lapidus fail to render obvious the invention of claims 9, 19 and 24.

Like claim 2, from which it depends, claim 7 relates to a method for detecting a current *Helicobacter pylori* infection; the method includes detecting a high-integrity *Helicobacter pylori* nucleic acid and identifying a patient as having a current infection if a relative amount of high-integrity *H. pylori* nucleic acid exceeds a reference relative amount. Applicant submits Gramley does not teach or suggest a method for detecting a current *Helicobacter pylori* infection; does not teach or suggest detecting a high-integrity *Helicobacter pylori* nucleic acid; and does not teach or suggest identifying a patient as having a current infection if a relative amount of high-integrity *H. pylori* nucleic acid exceeds a reference relative amount. Lapidus does not relate to the detection of a current *Helicobacter pylori* infection and does not teach or suggest detecting a high-integrity *Helicobacter pylori* nucleic acid or its use in detecting a current *Helicobacter pylori* infection. Accordingly, Applicant submits that even in combination Gramley and Lapidus fail to render obvious the invention of claim 2.

Applicant respectfully requests reconsideration and withdrawal of these rejections.

CONCLUSION

Claims 1-9, 17-20 and 24 are pending and presented for consideration. Examiner Chunduru is invited to telephone the undersigned agent to discuss any remaining issues.

Respectfully submitted,



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